MULTIDISCIPLINARY CLINICAL RESEARCH CAREER DEVELOPMENT PROGRAMS

RELEASE DATE: October 20, 2003

RFA Number: RFA-HD-04-006

Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATIONS:

National Institutes of Health (NIH)
(http://www.nih.gov)

This RFA is developed as an NIH Roadmap initiative (http://nihroadmap.nih.gov/). All NIH Institutes and Centers participate in roadmap initiatives. The RFA will be administered by the National Institute of Child Health and Human Development (NICHD) on behalf of the NIH.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER(S): 93.864

LETTER OF INTENT RECEIPT DATE: February 23, 2004
APPLICATION RECEIPT DATE: March 23, 2004

THIS RFA CONTAINS THE FOLLOWING INFORMATION

PURPOSE OF THIS RFA

The purpose of this RFA is to support the early career development of clinical researchers from a variety of disciplines engaged in all types of clinical research, including patient-oriented research, translational research, small- and large-scale clinical investigation and trials, and epidemiologic and natural history studies. These individuals would be expected to achieve excellence in their ability to design and oversee research in multidisciplinary team settings, and have a high potential to become leaders of various fields of clinical research critical to the overall mission of the National Institutes of Health (NIH). To accomplish this aim, the NIH invites institutions with well-established clinical research infrastructures to submit applications for the establishment of Multidisciplinary Clinical Research Career Development Programs.

The Program will train and foster the career development of individuals with doctoral-level professional degrees to become the next generation of clinical researchers who will perform clinical investigation in multidisciplinary, collaborative clinical research settings. Career Development Programs supported under this RFA must include a broad representation of clinical disciplines and professions (e.g., internal medicine, surgery, pediatrics, obstetrics/gynecology, dentistry, pharmacy, statistics, nursing, psychology) and their various specialties and sub-specialties. Programs must include a structured core didactic component and a practical training component in various aspects of the design, conduct, and analysis of clinical research. Individuals should be trained in team research settings and will be known as NIH Clinical Research Scholars (CR Scholars).

RESEARCH OBJECTIVES

Background

The National Institutes of Health (NIH), in keeping with its mission, is engaged in a series of initiatives collectively known as the "NIH Roadmap" (http://nihroadmap.nih.gov/), the goal of which is to accelerate both the pace of discovery of new knowledge in the prevention, detection, diagnosis and treatment of disease and the translation of these discoveries into applications that will improve the health of the nation. The objective of this initiative is to enhance the career development and training of postdoctoral and junior faculty health professionals in multidisciplinary, team research settings for leadership roles in the design and oversight of future clinical investigation. The overarching goal is to promote clinical investigation that will have a significant impact on improving health and preventing disease. For the purpose of this initiative, "clinical research" refers to all aspects and kinds of clinical research including, for example, epidemiologic and natural history studies, translational research, patient-oriented research, clinical trials, and outcomes research. Clinical research embraces a spectrum of scientific disciplines (e.g., epidemiology, statistics, pharmacology, biology, and psychology), methodologies (e.g., observational, experimental), health professions

(e.g., radiology, nursing, dentistry, clinical psychology), and specialties and sub-specialties (e.g., internal medicine, surgery, pediatrics, obstetrics/gynecology, oncology, cardiology, nephrology, and others).

Clinical research is a complex endeavor that is ideally performed by a multidisciplinary team using an integrated team approach. A multidisciplinary approach brings experts from diverse disciplines (for example, clinician, clinical trialist, statistician, medicinal chemist, and pharmacologist) to address collectively a common complex problem. There is a well-recognized shortage of well-trained physicians and other health professionals (e.g., dentists, behavioral scientists, clinical pharmacologists, statisticians, nurses, study coordinators, and data managers) performing clinical research in a rigorous, highly collaborative, team-oriented environment. This initiative will support the development and implementation of integrated Multidisciplinary Clinical Research Career Development Programs (referred to as Program in the following) that provide CR Scholars with knowledge and skills of the discipline of clinical research that are applicable to all diseases and organ systems. Programs should be designed to provide a flexible and efficient entrance into clinical research for doctoral-level individuals with a variety of disciplinary, specialty, or sub-specialty backgrounds, should emphasize the development of the entire clinical research team, and should reflect the prolonged time to develop and support the development of competent and independent clinical researchers. By providing this career development experience in a multidisciplinary setting, it is hoped that those completing the Program will be better prepared for the multidisciplinary real world requirements of clinical research.

Specific Objectives

The objectives of these new Career Development Programs are: (1) to stimulate and accelerate collaborative, multidisciplinary clinical research training and education; (2) to enhance the career development and training of scientists with doctoral-level professional degrees, who represent a broad range of disciplines, professions, specialties and sub-specialties including physicians, epidemiologists, behavioral scientists, biostatisticians, pharmacologists, dentists, nurses, and psychologists and others who can develop into the future leaders in all areas of clinical research; and (3) to establish a critical mass of national Programs devoted to developing an integrated, multidisciplinary and diverse workforce that will meet the current and future clinical research needs of the nation.

Individuals will be trained in team research settings. Programs will include didactic and practical training in various aspects of the design, conduct and analysis of clinical research with the goal of advancing clinical research in complex areas of medicine and promoting the conduct of research in highly collaborative settings. Programs must develop and propose a core didactic curriculum that will be presented to all first-year CR Scholars. Examples of a multidisciplinary core curriculum include:

o Clinical research methodology (including hypothesis generation, protocol design, etc.)
o Epidemiology
o Biostatistics
o Informatics
o Ethical issues in clinical trials (e.g., informed consent)
o Ensuring the safety of subjects in clinical trials
o Compliance with regulatory requirements for clinical research
o Team leadership and management
o Grant writing
o Interactions with industry

The first year of each CR Scholar's program should be dedicated primarily to core curriculum that must include a multi-disciplinary aspect to foster interactions among CR Scholars and faculty from various disciplines. The curriculum should link to other available clinical research training programs at the institutions, such as a K30 program, or a General Clinical Research Center program, or individual research fellowship programs supported by the NIH. The Program must demonstrate the flexibility to accommodate multiple disciplines and CR Scholars with different levels of education, training, and didactic and research experience. CR Scholars may obtain a certificate or degree upon completion of the Program (see below).

The second through (up to) fifth year of each CR Scholar's program should consist of: (1) a "hands-on" research experience (e.g., protocol development, data analysis planning, preparation of IRB applications, clinical research/trial management including patient accrual, data analysis, and report writing) in an existing team clinical research setting available at the institution, and (2) developing a clinical research project to provide experience in grant writing and project management.

While the institution is expected to have sufficient ongoing clinical research projects to fulfill this requirement, it may lack specific shared clinical research support elements. Therefore, Programs may ask for funding to develop additional shared clinical research support facilities critical to the conduct of team research, including, for example, specialized expertise in clinical research design and/or statistics, or a pool of study coordinators (see below) to be used by the CR Scholars.

MECHANISM OF SUPPORT

This RFA will use the NIH Mentored Research Scientist Development Program Award (K12) mechanism. See the SUPPLEMENTARY INSTRUCTIONS section for additional information. Applicants may request a project period of up to five years. The anticipated award date is September 30, 2004.

The Program Director will be solely responsible for planning, directing, and executing the proposed project. This RFA is part of the NIH Roadmap activities. At the end of the five-year project period, acceptance of applications for competing renewals or for new Programs will be based on the success of the program and at the discretion of Director, NIH, together with the Directors of the Centers and Institutes comprising the NIH.

FUNDS AVAILABLE

NIH intends to commit approximately $7 million in total costs [direct plus Facilities and Administrative (F&A) costs] for the first year of support of the Program. It is anticipated that up to five awards will be made in FY 2004, with five additional new awards in FY 2005 through a subsequent re-issuance and re-competition of this program.

In the first year of the award, an applicant may request up to $1.25 million direct costs. These funds would support an initial six-month planning/recruitment phase for $250,000 direct costs and $1.0 million direct costs to support the training of approximately five to eight CR Scholars. The $1.0 million will be restricted until the receipt and successful administrative review of the six-month progress report; the restricted funds will then be made available for expenditure. The Notice of Grant Award will be issued no later than September 30.

For the second year, applicants may request up to $2.17 million in direct costs, which is intended to support a total of approximately 12-15 CR Scholars. Subsequent yearly awards may be requested for up to $3.7 million in direct costs, which are intended to support a total of approximately 20-25 CR Scholars. When fully implemented, each K12 award will provide for up to $3.7 million direct costs per year to support a total of approximately 20-25 CR Scholars per year. F & A costs for these awards are limited to eight percent of modified total direct costs.

ELIGIBILE INSTITUTIONS

You may submit an application if your institution has any of the following characteristics:

o For-profit or non-profit organizations
o Public or private institutions, such as schools of medicine, schools of public health or schools of dentistry or other health professional schools, or other institutions of higher education
o Domestic institutions/organizations
o Foreign institutions and foreign collaborations are not eligible for this award.

An eligible institution (e.g., university) may submit only a single application in response to this RFA. Multiple applications from different divisions, faculties, centers, schools, etc. at the same university will be returned without further consideration by the NIH.

Applicant institutions must have strong clinical research faculty representing a broad spectrum of clinical disciplines, specialties, and sub-specialties; sufficient ongoing clinical research projects to serve as the platform for active participation of CR Scholars; extensive clinical research facilities; and a strong track record of competing for clinical research support to meet the purposes of this Program, namely, to encourage/enhance clinical research training and career development that promotes health and prevents disease. Collaborating institutions may be included to supplement training activities in needed areas.

INDIVIDUALS ELIGIBLE TO BECOME PROGRAM DIRECTORS

The Program Director will be responsible for planning, directing, and executing the proposed Career Development Program for the institution. Program Directors should have a strong and active track record in clinical research, clinical research training, and administration that demonstrates the skills, knowledge, and experience necessary to develop and manage the proposed Career Development Program. Individuals from underrepresented racial and ethnic groups, persons with disabilities, and women are always encouraged to apply as Principal Investigators for NIH programs.

ELIGIBLE SCHOLARS

Clinical Research Scholar (CR Scholar) positions are open to health professionals with doctoral-level degrees, but distinct from clinical fellowships with specific requirements leading to clinical certification. Scholars for support as CR Scholars must: (1) be US citizens or noncitizen nationals, or must have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-155) or some other verification of legal admission as a permanent resident. Individuals on temporary or student visas are not eligible; (2) have a clinical doctorate or Ph.D. degree or its equivalent; (3) be able to commit at least 50-75 percent of full-time professional effort in this Career Development Program and its related clinical research activities; (4) have a mentor with extensive clinical research experience; (5) not be or have been a Principal Investigator on an R01 or R21 award or on a subproject of a Program Project (P01), Center (P50, P60, U54), mentored career development (K-series) grants, or other equivalent research grant awards. Scholars may have had support on a NRSA grant (F or T) or NIH small grant (R03).

Clinical doctorate degrees include, but are not limited to, the M.D., D.P.H., D.O., D.D.S., D.M.D., O.D., D.C., Pharm.D., N.D.(Doctor of Naturopathy), Ph.D., Psy.D., as well as epidemiologists, behavioral scientists, and nurses with doctoral degrees.

The K12 award will provide for a minimum of two years and a maximum of five years of consecutive funding for each CR Scholar, consisting of consecutive 12-month appointments. In general, at least 75 percent of the CR Scholars' full-time professional effort must be devoted to the K12 Program per se. The remainder of the recipient CR scholar's time may be devoted to developing other clinical or academic pursuits that are

consistent with the objectives of the award. Certain clinical specialties may have less than 75 percent effort, but no less than 50 percent effort for the K12 program if sufficiently justified (for example, surgical specialties requiring 50 percent direct patient care time to keep up surgical skills).

CR Scholars may receive a certificate of completion or an advanced degree (if applicable). CR Scholars are encouraged to apply to the NIH Loan Repayment Program (http://www.lrp.nih.gov/).

SPECIAL REQUIREMENTS

Applicants are strongly encouraged to contact NIH Program Staff well in advance of the letter of intent submission date to discuss their proposed Career Development Program. There will be a Program website, FAQ's, Listserve, and a pre-submission National meeting (and videocast) to disseminate information about this Program. Applicants are invited to arrange a pre-application consultation with NIH Program Staff. These contacts will assure that the applicants have a thorough understanding of the intent and expectations of this RFA before they engage in the development of an application. These activities are described in the section WHERE TO SEND INQUIRIES.

The NIH recognizes that individual institutions will be positioned to respond in different ways to the opportunities presented in this RFA. However, all Programs are expected to provide multidisciplinary clinical research career development experiences for the CR Scholars.

A. Special Programmatic Requirements

Applicants must address the following specific program elements:

1. Overall Approach: Career Development Programs must have a strong and broad base of on-going clinical research. The Program must offer clinical research training that crosses at least four disciplines (for example, clinical research design, epidemiology, statistics, pharmacology, informatics, behavioral science). The Program must include two phases: (1) a didactic clinical research education component, and (2) a practicum phase in which clinical research is performed under the guidance of a qualified mentor or mentors. Although the first phase will address general core issues, the practicum will be tailored to the background and interests of the CR Scholar. The focus of the Program must not be restricted to a single problem, but rather should be dispersed across multiple health conditions and not be restricted to a single disease or health problem (e.g., cardiovascular disease, cancer, diabetes, etc.).

During the practicum phase, we expect that an individual CR Scholar's research projects may be focused on a single disease or health problem. The Program phases are described in more detail below. The intent is to provide didactic training before the practicum, but the phases might overlap if sufficient justification is provided.

The Program should have a broad focus and representation from multiple disciplines and specialties. The CR Scholars, Advisory Panel Members, and Mentors should come from a diverse range of disciplines, specialty, and sub-specialty areas. Each yearly class should include CR Scholars whose backgrounds span at least two to three disciplines, specialty, and sub-specialty areas. When fully implemented, the Program should have CR Scholars in at least four disciplines.

2. Program Director: The Program Director must be a senior faculty member or Director of a research center or multidisciplinary institute, who possesses the scientific background, leadership, and administrative capabilities required to coordinate and supervise a multidisciplinary clinical Research Career Development Program of this scope. The application may include co-director(s) from the same institution or from partnering or collaborating institutions. These co-director(s) should be experienced investigators who have administrative skills and backgrounds that complement those of the PI.

3. Multidisciplinary Advisory Committee (MAC): The Program Director must appoint and chair a permanent Multidisciplinary Advisory Committee. The MAC would be responsible for recruiting and selecting CR Scholars to the Program; establishing and reviewing the core curriculum; approving the education and career development plans (e.g., curriculum, mentors, research experience) and customizing an individual career development program for each CR Scholar; providing interim monitoring and evaluation of each CR Scholar's progress with recommendations for modifications in the plan, if necessary, or termination of a CR Scholar who is not making adequate progress; and monitoring and evaluating the overall effectiveness of the Program. The MAC may set criteria to award graduates of the Program a certificate of completion. The MAC should meet regularly and keep written minutes, which may be reviewed as part of an NIH site visit, or in review of a competing or non-competing continuation application. The MAC would provide a summary annual progress report of the Program's development, including an evaluation of areas of strengths and weaknesses.

The MAC or a subgroup of the MAC, which can be supplemented with additional expertise either from within or outside of the institution, will also be responsible for conducting the peer review of clinical research projects submitted by the CR Scholars during the final stage of their Practicum Phase/Mentored Research Experience. The purpose of these projects will be to introduce the CR Scholars to the planning and preparation of a research project, to allow the CR Scholar to make revisions of the project in response to peer review, and to allow the CR Scholar to develop preliminary results that can form the basis for an independent research program. Projects supported from this grant are expected to comply fully with all Federal policies, rules, and guidelines applicable to research involving human subjects and animals.

4. Mentors: Each CR Scholar appointed under the K12 award must be supervised by a mentoring team of at least two mentors from different disciplines or specialties (for example, one clinical/translational and the other basic science; or a sub-specialist clinical researcher and a clinical trialist). The primary mentor should be recognized as an independent investigator and be actively involved in clinical research, and demonstrate a successful track record of mentoring and providing research training and career development of a type expected in this Program. The mentors must be committed to continue this involvement with the CR Scholar for the duration of his/her appointment on this Career Development Program. Each program should have a representative sample of mentors, at least 25.

5. Clinical Research Capability and Infrastructure: The institution must demonstrate that it has a broadly funded clinical research base, the infrastructure to support clinical research (for example, GCRC, biostatistics expertise, etc.), and the facilities (e.g., inpatient and outpatient facilities, affiliate hospitals etc.) and patient resources to address multiple diseases and health conditions.

6. Planning Phase: All Programs must propose a six-month Planning Phase in a special section of the application with clear, quantifiable targets or milestones for establishing management procedures, developing and implementing required infrastructure necessary to complement existing infrastructure needed for the Program, integrating all infrastructure of the Program so it works in a unified manner, and initiating recruitment plans for bringing CR Scholars into the Program. Completion of the Planning Phase (i.e., reaching the proposed milestones) will result in the release of restricted funds for the first five to eight CR Scholars who will begin their training in the first year of the Program.

7. Didactic Clinical Research Curriculum: Each CR Scholar must first receive didactic training in an extensive core curriculum that should include, for example, course work in epidemiology, behavioral science, study design, statistics, regulatory compliance, bioethics, responsible conduct of research, mentoring, leadership and team building skills. These courses should be designed to be taken by the entire multidisciplinary group of CR Scholars. The curriculum can be individualized, depending upon the level of experience of the CR Scholar. For example, CR Scholars with sufficient expertise that is well documented in a specific area (e.g., statistics) may be exempted from that aspect of the core curriculum by demonstrating mastery of that area.

In addition, Programs should propose career development opportunities such as regular journal clubs, seminars, grand rounds, and other forums designed specifically for CR scholars. These should facilitate the exchange of ideas, collaboration among scholars, and networking opportunities among CR scholars, mentors, and the Program Director.

CR Scholars are expected to take specific training modules that are individually tailored to their specific training needs. In addition, courses may be offered for the training of mentors in leadership, management, and team building.

8. Practicum Phase/Mentored Research Experience: The mentored/team research experience must last a minimum of one year. This practicum phase may be divided into two parts:

a) Participation in an ongoing clinical research project. The CR Scholar will be an active team member, working alongside the mentor/team lead.

b) Development and implementation of a new research project by the CR Scholar under the guidance of a mentor(s). The CR Scholar will write a research proposal, which will be reviewed and approved by the MAC. It is expected that the project will receive ongoing support by the Shared Research Support Facility (described below), and sufficient oversight by the primary mentor. The application should describe the process and review criteria, including the application, review, oversight, and evaluation procedures, and adherence to all Federal rules and guidelines regarding clinical research.

9. Shared Clinical Research Support Facility: The applicant should provide evidence of existing specialized shared clinical research support facilities that aid CR Scholars in developing and managing their research projects. The applicants should also provide an analysis to indicate what infrastructure resources are needed, and a plan for acquiring and implementing them. With strong justification, a Shared Clinical Research Support Facility may be requested as part of the Career Development Program, within the total Budget Request. The Facility may include, for example, a research design incubator with statistical expertise, a shared pool of study coordinators to work with the CR Scholars, or a module for curriculum development and evaluation. The Shared Clinical Research Support Facility must be a separate entity, not an extension or enhancement of an individual investigator's laboratory. The design of the new shared facility will be influenced by the type of research conducted at the institution and will build upon the specific strengths of existing programs (e.g., K30 and GCRC programs, program project and Center grants, or similar elements).

10. Institutional Commitment: Applicant institutions should show commitment to the Program's goals, and provide assurances that the institution intends the Program to be an integral part of its research endeavor. Research facilities and training opportunities will be a critical part of the environment. Institutional commitment in support of the proposal must be obtained by letters from high-ranking institutional officials that: (1) describe how the proposed Program will be an integral component of the institution's broader vision with respect to clinical research; (2) outline how institutional barriers for clinical research and clinical researchers will be or are being addressed (i.e., promotion and

tenure, etc.); and (3) provide a guarantee of 75 percent protected time (or at least 50 percent in certain cases) for the CR Scholars. The letters should supply evidence of an active clinical research faculty, statistical and epidemiologic support, basic science support for clinical research questions, and associations with schools of medicine and/or public health, departments of behavioral and/or social sciences, and other resources.

11. Integration with Other Related Institutional Programs: Interaction and overlap with existing local clinical research training infrastructure (Schools of Public Health, departments, K30 awards, etc.) should be identified and clarified, and integrated into a single, unified institutional Program. Applications should also describe interactions with GCRCs and existing disease-focused NIH-funded Centers and other clinical research programs (Program Project grants, Center grants, Foundation-sponsored Centers, etc.).

12. Evaluation and Tracking Component: The applicant should describe a strong evaluating and tracking component, that will review the effectiveness of all aspects of the Program (including courses, mentors, MAC members, PI), and a system for tracking graduates throughout their career to determine the success rate of applying for and obtaining Federal and non-Federal research grant support. This should include enrollment and appointment information (diversity of backgrounds, disciplines and specialties) and outcomes measures (academic placement, clinical vs. basic science research), etc.

13. Recruitment Plan: Applicants must submit a recruitment plan that includes a scheme for: (1) recruiting CR Scholars from both outside and inside their institution(s), and (2) recruiting under-served and under-represented minority and ethnic populations. Programs are encouraged to collaborate with minority-serving institutions.

Minority Recruitment and Retention Plan: The NIH remains committed to increasing the participation of individuals from underrepresented minority groups in biomedical and behavioral research. All competing applications for this Program must include a specific plan to recruit and retain underrepresented minorities in the Career Development Program. In addition, all competing continuation applications must include a report on the recruitment and retention of underrepresented minorities during the previous award period. If an application is received without a plan or without a report on the previous award period, the application will be considered incomplete and will be returned to the applicant without review.

Competing continuation applications and Non-competing Grant Progress Reports must include a detailed account of experiences in recruiting individuals from underrepresented groups during the previous funding period. Information must be included on successful and unsuccessful recruitment strategies. The report should provide information on the racial/ethnic distribution of:

o All Scholars who applied for admission or positions within the department(s) participating in the Program
o Scholars who were offered admission to or a position within the participating department(s)
o Scholars actually enrolled in the participating departments
o CR Scholars who were appointed to the Program

For those Scholars who were enrolled in the Program, the report should include information about the duration of research training and whether those Scholars finished their training in good standing.

The success of efforts to recruit and retain minority Scholars is a factor in the assessment of the quality of the Scholar pool and, thus, will be included in determining the priority score. In addition, peer reviewers will separately evaluate the minority recruitment plan and report (for competing renewals) after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of minorities and whether the experience in recruitment during the previous award period has been incorporated into the formulation of the plan for the next award period. The review panel's evaluation will be included in an administrative note in the summary statement. If the plan or the record of minority recruitment and retention is judged to be unacceptable, funding will be withheld until a revised plan (and report) that addresses the deficiencies is received. NIH Staff will determine whether amended plans and reports submitted after the initial review are acceptable.

14. Participation in a National Program: Programs will be expected to interact extensively with the NIH and other Multidisciplinary Clinical Research Career Development Programs, and be part of a National Clinical Research Career Development effort that is part of NIH's Roadmap Program to Re-engineer the Clinical Research Enterprise. The NIH will facilitate communication among the Program Directors via phone calls, a Listserve (http://list.nih.gov/archives/clinrescareers.html), and a Program website (http://www.nichd.nih.gov/RFA/HD-04-006/roadmap.htm). NIH will host a planning meeting within the first month of the Program. Attendance at an annual meeting of the Program Directors and CR Scholars with the NIH staff will be required for the purpose of sharing information and making midcourse corrections that will improve Programs. NIH Program Staff will conduct periodic site visits, will review each site's progress in meeting its overall goals, and provide financial oversight of the Program. Proposed CR Scholars will be selected by the MAC, with review and final approval by NIH Program Staff. The Program Director will then submit appointment forms for each CR Scholar to the NIH. Applicants must notify NIH if there is a change in PI, co-PI, or a CR Scholar's mentor.

B. Budget and Related Issues

Allowable Costs:

1. Salary: The NIH will provide support for each CR scholar position up to the NIH legislative cap toward salary, and associated fringe benefits. The total salaries must be based on a 12-month appointment and the level of effort related to the K12 program activities. The institution may supplement the NIH salary contribution up to a level that is consistent with the institution's salary scale from non-Federal sources. In all cases, salaries requested must be consistent with the level of effort, with the established salary structure at the institution, and with salaries actually provided by the institution from its own funds to other staff members of equivalent qualifications, rank, and responsibilities in the department concerned. If full-time, 12-month salaries are not currently paid to comparable staff members, the salary proposed must be appropriately related to the existing salary structure.

2. Personnel Costs for Program Director and Mentors: Up to 40 percent of the Program Director's salary and fringes for first six months, then up to 20 percent per year. Mentors may be paid up to $5,000 per year (up to two mentors per CR Scholar). Salary for faculty to develop and implement needed core clinical research curricula and training modules may be included.

3. Other Expenses: The K12 may be used toward the following expenses: (1) Travel for Program Director and co-director (if applicable) to the initial meeting in October 2004; (2) tuition, fees, and books related to career development; (3) travel for Program Director, co-director (if applicable), and CR Scholars to the annual NIH meeting for CR Scholars; (4) travel to one additional training or scientific meeting per year; (5) recruitment costs (up to $3,000 per year) to attract CR Scholars who can excel in and potentially become leaders in clinical research.

4. Research Project Support: Applicants should request a pool of money, representing typically $25,000 per year per CR Scholar, that will be used to augment his/her research project support during training and/or provide support for a project designed by the CR Scholar. This money, typically $25,000 (and up to $50,000 in exceptional circumstances) per year, can be used for (1) research expenses, such as supplies, equipment, and technical personnel; (2) statistical services including personnel and computer time; and (3) other project infrastructure including relevant data sets.

5. Shared Clinical Research Support Facility: Applicants may request money, totaling up to $100,000 in the first year and up to $200,000 at full implementation, to set up new specialized shared training facilities that complement existing clinical research infrastructure. These facilities may provide technical training support to aid CR Scholars

in developing and managing their research projects. These might include, for example, research design incubators with statistical expertise, a shared pool of study coordinators to work with the CR Scholars, or a curriculum development module.

6. Facilities and Administrative Costs: These costs will be reimbursed at eight percent of modified total direct costs.

7. Other Income: Fees resulting from clinical practice, professional consultation, or other comparable activities by the research and research-related activities of this award may not be retained by the career award recipient. Such fees must be assigned to the grantee institution for disposition by any of the following methods: (1) The funds may be expended by the grantee institution in accordance with the NIH policy on supplementation of career award salaries and to provide fringe benefits in proportion to such supplementation. Such salary supplementation and fringe benefits must be within the established policies of the grantee institution. (2) The funds may be used for health-related research programs. (3) The funds may be paid to miscellaneous receipts of the U.S Treasury. Checks should be made payable to the Department of Health and Human Services, NIH and forwarded to the Director, Office of Financial Management, NIH, Bethesda, Maryland 20892. Checks must identify the relevant award account and reason for the payment.

Awardees may retain royalties and fees for activities such as CR Scholarly writing, service on advisory groups, or honoraria from other institutions for lectures or seminars, provided these activities remain incidental and provided that the retention of such pay is consistent with the policies and practices of the grantee institution.

Funds budgeted in an NIH-supported research or research training grant for the salaries and/or fringe benefits of individuals, but freed as a result of a K12 award, may not be rebudgeted and may not be used for any other purpose without prior NIH approval.

8. Carryover of Unobligated Balances: Although the K12 award is subject to Expanded Authorities, the carryover of funds from one budget period to the next requires prior written approval by the NIH funding component. The one exception to this is that carryover of funds from one fiscal year can only be to support the career development of an identified CR Scholar.

C. Special Reporting Requirements

The K12 award is not subject to the streamlined non-competing application process (SNAP). In general, this means that all reporting of budgetary information and Program progress is provided in greater detail in an annual progress report.

1. Progress Reports: An Annual Progress Report is required. This report should provide information about changes in the Program, a summary report of the evaluation of the

Advisory Committee, and a description of the research and career progress of each CR Scholar. These Annual Progress Reports will be closely monitored by NIH staff to ensure that the grant is achieving the goals of the Program.

Progress reports are submitted using the Form PHS 2590, which can be obtained at the following website address: http://grants.nih.gov/grants/funding/2590/2590.htm. Since the Form PHS 2590 does not apply easily to the K12 grant, adapt the application for continuation to contain the following information:

o Appropriate Face Page A as instructed in the Form PHS 2590.

o A budget page B that provides the salary and fringe benefits for each CR Scholar by name or by position if no individual is filling the position at the time of the application. Provide all other budgetary information (e.g., supplies, travel, technical help) broken out specifically for each CR Scholar up to the limit.

o A brief description of the Objectives and Goals of the Program.

o A brief summary listing by name delineating which faculty, mentors, and Advisory Committee members have left the Program and which new individuals have been added or are taking their places. Include for each person his/her degree and department affiliation (or equivalent).

o Biographical sketches of 1) new faculty, 2) new mentors, 3) new MAC members, 3) new CR Scholars.

o Progress of Individual Scholars: A brief paragraph for each CR Scholar describing the research and didactic training experiences completed and ongoing, as well as the specific future plans for satisfying the core requirements of the Program.

o List of publications for each Scholar resulting from their work in the Program.

o A detailed account of experiences in recruiting individuals from underrepresented groups during the previous funding period (see above).

o Summary information on the Program; a sample table can be obtained from the NICHD Program Staff.

o A Report from the MAC that is separately attached summarizing the actions of the MAC during the last year, evaluating the performance of the Program in meeting its objectives and intent, evaluating the effectiveness of recruitment strategies (provide a separate evaluation for minority recruitment), and providing recommendations for improving the Program (e.g., new mentors, changes in core requirements, changes in recruitment strategies etc.)

2. Final Reports: A final progress report, invention statement, and Financial Status Report are required upon termination of an award or relinquishment of an award.

3. Evaluation: In carrying out its stewardship of human resource-related programs, the NICHD may request information essential to an assessment of the effectiveness of this Program. Accordingly, recipients are hereby notified that they may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the Program.

D. Special Administrative Requirements

1. Special Leave: Leave to another institution for a Scholar, including a foreign laboratory, may be permitted if directly related to the purpose of the award. Only local, institutional approval is required if such leave does not exceed three months. For longer periods, prior written approval of NICHD staff is required. To obtain prior approval, the Scholar must submit a letter to NICHD Program Staff describing the plan, countersigned by his or her department head and the appropriate institutional official. A copy of a letter or other evidence from the institution where the leave is to be taken must be submitted to assure that satisfactory arrangements have been made. Support from the award will continue during such leave.

Leave without award support may not exceed 12 months. Such leave requires the prior written approval of the NICHD and will be granted only in unusual situations. Support from other sources is permissible during the period of leave. Parental leave will be granted consistent with the policies of the NICHD and the grantee institution.

2. Termination: When a grantee institution plans to terminate an award, the NICHD must be notified in writing at the earliest possible time so that appropriate instructions can be given for termination.

3. Change of Institution: The Program cannot be transferred from one institution to another.

4. Change of Program Director: If the Program Director moves to another institution or resigns from the position, support of the award may be continued with NICHD prior approval, provided:

o The current Program Director or the awardee institution has submitted a written request for change of Program Director, countersigned by the appropriate institutional business official, to NICHD Program Staff describing the reasons for the change. The Biographical Sketch of the proposed new Program Director, including a complete listing of active research grant support, is provided. The information in the request

establishes that the specific aims of the original peer-reviewed program to be conducted under the direction of the new Program Director will remain unchanged, and that the new Program Director has the appropriate research and administrative expertise to lead the Program.

o The request is submitted far enough in advance of the requested effective date to allow the necessary time for review.

5. Changes of Program: Awards are made to a specific institution for a specific Program under the guidance of a particular Program Director. Changes in any of these parameters require prior approval by NICHD Program Staff. A scientific rationale must be provided for any proposed changes in the aims of the original peer-reviewed Program. The new Program will be evaluated by NICHD Program Staff to ensure that the Program remains within the scope of the original peer-reviewed Program. If the new Program does not satisfy this requirement, the award could be terminated.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. To disseminate information about this Program, the NIH has set up a Roadmap Website with FAQs (http://nihroadmap.nih.gov/), a website for this Program (http://www.nichd.nih.gov/RFA/HD-04-006/roadmap.htm), and a Listserve (http://list.nih.gov/archives/clinrescareers.html), and will have a National pre-submission technical support meeting in December 2003. In addition, applicants are encouraged to contact NIH Program Staff for a pre-application consultation to ensure that they have a thorough understanding of the intent and expectations of this RFA before they engage in the development of an application.

Inquiries may fall into three areas: programmatic, peer review, and financial or grants management.

o Direct your questions about GENERAL PROGRAMMATIC issues to:

Robert Star, M.D.
Senior Scientific Advisor
National Institute of Diabetes and Digestive and Kidney Diseases
Building 31, Room 9A-19C, MSC 2560
31 Center Drive
Bethesda, MD 20892-2560
Telephone: (301) 594-7717
E-mail: Robert.Star@nih.gov

Joan Davis, M.D., M.P.H.
Program Director
National Institute of Child Health and Human Development
Center for Population Research
6100 Executive Boulevard, Room 8B01, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 496-6515
E-mail: jd372m@nih.gov

o Direct your questions about peer review issues to:

Robert Stretch, Ph.D.
Director, Division of Scientific Review
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 5B01, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 496-1485
E-mail: stretch@nih.gov

o Direct your questions about financial or grants management matters to:

Ms. Annette Hanopole
Chief, Grants Management Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8A01, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 496-5001
FAX: (301) 480-4782
E-mail: hanopola@mail.nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

o Descriptive title of the proposed Program
o Name, address, and telephone number of the Program Director
o Names of other key personnel
o Participating institutions
o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by February 23, 2004. The letter of intent should be sent to:

Joan Davis, M.D., M.P.H.
Program Director, BIRCWH Program
Reproductive Sciences Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8B01, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 496-6515
E-mail: jd372m@nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the website at http://www.dunandbradstreet.com/. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

SUPPLEMENTARY INSTRUCTIONS:

The instructions in the Form PHS 398 do not fully apply to the special needs of this grant application. Therefore, follow the modified instructions below in preparing an application for a Multidisciplinary Clinical Research Career Development Program (K12). These instructions have been adapted to accommodate the PHS 398 and the special needs of the K12 grant:

1. Face Page: Use Form Page 1 of the PHS 398. On Line 1, include the title that best represents the nature of the Career Development Program. On Line 2, provide the number of this Request for Applications, RFA-HD-04-006, and the RFA title "Multidisciplinary Clinical Research Career Development Programs." The Program Director will be the Principal Investigator (PI) of the grant application.

2. Description/Performance Site(s)/Key personnel (Form Page 2 of PHS 398): Complete as directed in the PHS 398 instructions. The information provided should include the PI, Advisory Committee members, mentors, and other faculty participating in the Program.

3. The application should be organized as follows (when following this format, applicants should refer regularly to those sections of this announcement that delineate "special programmatic requirements" and "review criteria"):

A. Face Page

B. Description, Performance Sites, and Key Personnel

C. Table of Contents

D. Detailed Budget Page for Initial Budget Period: separate the budget for the first six months (i.e., Planning Phase) from the second six months (i.e., initial implementation phase for five to eight CR Scholars)

E. Budget for Entire Proposed Period of Support that escalates the number of Scholars to 12-15 in the second year and to 20-25 in the third, fourth and fifth years

F. Biographical Sketches in the standard NIH format for the Program Director, co-director(s), Multidisciplinary Advisory Committee (MAC) members, Mentors, and Other Faculty of this Program

G. Other Support: for the Program Director, Co-director(s), MAC members, Mentors, Other Faculty of this Program

H. Multidisciplinary Clinical Research Career Development Program (no more than 40 pages):

(1) Overall Aims

o Approach/Meeting the Intent of this Initiative

o Institutional Commitment

(2) Major Program Elements

o Clinical Research Capability and Infrastructure: Include plans for Shared Clinical Research Support Facility

o Program Leadership/Management

o Multidisciplinary Advisory Committee: Include plans for matching CR scholar to mentor; include policies and procedures for the Research Project Support Program

o Program Mentors/Team Leaders

o Description of Didactic Core Requirements and Practicum research experience

o Interactions

(3) CR Scholar Pool and Recruitment Plans

(4) Evaluation/Tracking

(5) Planning phase and milestones

I. Human Subjects

J. Vertebrate Animals

K. Checklist

L. Appendices and Tables: Suggested tabular formats for this information will be made available via the Program website and Listserve (See WHERE TO SEND INQUIRIES shown above). The following information should be included:

(1) Funded Training and Career Development Programs Relevant to Clinical Research. This should include all programs within the institution that are relevant to the purpose and objectives of the Program. (e.g., K30s, T32s, R25s, Ts, K12s, GCRCs, School of Public Health, Degree Programs, etc.). The table should be organized using the following headings: Principal Investigator, Source of Support (e.g., Institution, NIH, Other Federal agencies, non-federal support, Industry), Title, Health Focus (e.g., heart disease, child health, aging, mental health, cancer), number of Scholars, and Description (no more than two sentences).

(2) Existing Funded Clinical Research Support. This should include the overall total (for example, by type and Phase of research), and a table summarizing a representative sample (including at least 50 studies) of the clinical research currently being conducted in the Institution(s). The table should include: Principal Investigator, Source of Support (e.g., Institutional, NIH, other Federal, non-federal, Industry), Title, Research Emphasis (e.g., epidemiology, therapy, diagnosis, nutrition, behavior); Health Focus; Disciplines involved, Dates, Length, Total Costs.

(3) Clinical Research Infrastructure. This should include all shared clinical research facilities within the institution(s) (e.g., GCRCs, incubators, statistical expertise, etc.).

(4) Expertise and Training Track Record of Program Director, Co-directors(s), MAC members, Mentors, and Other Faculty. This should include name, rank, department/division, area of expertise, and other relevant information for the Program Director, Co-directors(s), and MAC members, as well as a representative sample of mentors (include at least 25 mentors) and other faculty members included in this Program. For each person, please include a list of five to ten recent Scholars (Scholar's name, degree, research project, current position, current research area, basic or clinical research).

(5) Clinical Facilities, Patients, and Specialized Populations. This should include all hospitals and in-patient and out-patient clinics; a numerical distribution of patients relative to disease and/or health issues; and specialized populations that are served by the institutions in this Program.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/labels.pdf.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Robert Stretch, Ph.D.
Director, Division of Scientific Review
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 5B01, MSC 7510
Bethesda, MD 20892-7510
Rockville, MD 20852 (for express/courier service)

APPLICATION PROCESSING: Applications must be received on or before the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight weeks.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to an RFA, it is to be prepared as a NEW application. That is, the application for the RFA must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and for responsiveness by the NIH Program Staff. Incomplete or unresponsive applications will not be reviewed.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NICHD in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

o Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority scoreo Receive a written critique

o Receive a second level review by the National Advisory Child Health and Human Development Council.

REVIEW CRITERIA

The goal of this Career Development Program is to ensure that highly trained clinical researchers will be available in adequate numbers and in appropriate research areas to enhance the clinical research enterprise for the conduct of clinical investigation. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed Program will have a substantial impact on the pursuit of these goals.

o Approach/Meeting the Intent of this Initiative
o Institutional Commitment
o Clinical Research Capability and Infrastructure
o Program Leadership/Management

o Multidisciplinary Advisory Committee
o Program Mentors/Team Leaders
o Didactic Core Requirements
o Interactions
o Scholar Pool and Recruitment Plans
o Evaluation/Tracking
o Planning Phase

The scientific review group will address and consider each of these criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major scientific and technical merit and thus deserve a high priority score.

(1) APPROACH/MEETING THE INTENT OF THIS INITIATIVE: The adequacy of the
overall Program strategy from the planning to the full implementation phase in satisfying the intent of this initiative to develop and sustain a high quality Career Development Program that addresses a wide range of clinical disciplines, specialties, and sub-specialties. Does the Program provide excellence in the design and conduct of clinical research and training? Will the Program prepare CR Scholars to become potential leaders in clinical research? Does the Program take maximum advantage of existing didactic capabilities, clinical infrastructure, and faculty strengths?

(2) INSTITUTIONAL COMMITMENT: Is the institutional leadership committed to this program and its goals? Does the institution provide assurances that the institution intends the Program to be an integral part of its research endeavor, and that clinical research facilities and training opportunities will be a critical part of the environment? Have institutional barriers for clinical research and clinical researchers been adequately addressed? Adequacy of cooperative arrangements between consortium institutions, if applicable, that will ensure that the Program performs effectively as one activity across institutional boundaries. Does this Program cross all departments and integrate all clinical research training programs and clinical research infrastructure elements within the institution, to benefit the entire institution? Is there adequate commitment of the institution(s) from the institutional leadership to Department Chairs to protect the time of Scholars, guarantee 50 to 75 percent professional effort of each CR Scholar, actively engage in the promotion of each CR Scholar's clinical research career, and support the career and tenure process for clinical researchers at the institution?

(3) CLINICAL RESEARCH CAPABILITY AND INFRASTRUCTURE: The adequacy of the overall clinical research and training environment and track record of the institution(s) in conducting interactive, multidisciplinary, collaborative, peer-reviewed clinical research (e.g., translational research, Phase I, II, and III therapeutic trials, epidemiological studies, etc.) involving a broad range of clinical disciplines and diseases. The adequacy of the existing infrastructure of the institution(s) (e.g., cores for biostatistics, informatics, data management, research nurses, data managers) supported by

NIH (e.g., GCRCs) and other sources. Are there sufficient plans to improve and complement the existing infrastructure, and to integrate infrastructure and eliminate overlap in order to support a high quality Career Development Program in clinical research? Are the plans for the Shared Clinical Research Support Facility adequately justified?

(4) PROGRAM LEADERSHIP/MANAGEMENT: Does the Program Director have the
necessary recent clinical research background and administrative qualifications and experience to provide scientific leadership, management, and coordination of a clinical research Career Development Program of this size and complexity? Have the Program Director and co-director(s) committed sufficient time to devote to this Program? Will the Program Director have sufficient authority and credibility in the Institution to work across institutional boundaries?

(5) MULTIDISCIPLINARY ADVISORY COMMITTEE: Are MAC members sufficiently experienced and representative to oversee this multidisciplinary Career Development Program? Have the MAC members committed sufficient time to meet the needs of the Program? Will the MAC procedures and processes adequately select, monitor, and evaluate the CR Scholars and the overall Program? Are there adequate procedures described for selecting and replacing MAC members? Will the process and review criteria for evaluating the CR Scholar's clinical research projects meet the high scientific standards of an NIH review? Will they be adherent to all applicable Federal rules and regulations?

(6) PROGRAM MENTORS/TEAM LEADERS: Are the mentors and team leaders who will participate in this Program clearly delineated, do they have the experience, skills, and track record at mentoring necessary to provide CR Scholars with high quality multidisciplinary, team-oriented research training, and do they broadly represent the disciplines, specialties, and subspecialties necessary to make this Program work effectively? Will the mentors commit sufficient time to ensure the success of the Program?

(7) DIDACTIC CORE REQUIREMENTS: Are the didactic requirements sufficient to train CR Scholars to lead, design, and conduct clinical research, and work effectively in collaborative teams? Have the various didactic resources within the institution (e.g., departmental, NIH-supported K30s and GCRCs) been integrated and extended, as necessary (e.g., specialized courses and shared facilities), to effectively meet the needs of the Program? Does the Program have adequate flexibility to accommodate CR Scholars with different levels of experience?

(8) INTERACTIONS: Commitment of the applicant to work with other Programs and the NIH as reflected by their proposed ideas to improve performance and outcomes. Commitment to share best practices and to participate in the NIH Roadmap program (http://nihroadmap.nih.gov/) to improve the National clinical research enterprise.

(9) SCHOLAR POOL AND RECRUITMENT PLANS: Does the application demonstrate well-defined recruitment procedures, potential sources, and number of high-quality Scholars, CR Scholar selection criteria, and retention strategies? Are these processes adequate to achieve a high-quality pool of CR Scholars representative of a broad range of clinical disciplines, specialties, and sub-specialties? Does the Program seek to recruit CR Scholars from outside the institution? Adequacy of plans to recruit women and members of underrepresented racial/ethnic minorities.

(10) EVALUATION/TRACKING: Adequacy of the plans for the MAC and/or other procedures to evaluate the performance of the Program as a whole (e.g., quality of the didactic cores, adequacy of the performance of mentors, adequacy of faculty participation), and to make changes that improve performance and outcomes. Adequacy of the plans to track career outcomes of CR Scholars, including positions held, papers published, grants and awards submitted/obtained, and other relevant information.

(11) PLANNING PHASE: If all milestones are met during the planning phase, will this be sufficient to implement the program after six months?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below.)

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below.)

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL CONSIDERATIONS

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH: The appropriateness of topics, format, amount, and nature of faculty participation, and the frequency and duration of instruction. Every Scholar supported by these grants must receive instruction in the responsible conduct of research. For more information on this

provision, see the NIH Guide for Grants and Contracts, Volume 21, Number 43, November 27, 1992, see http://grants.nih.gov/grants/guide/notice-files/not92-236.html . Applications must include a description of a program to provide formal or informal instruction in scientific integrity or the responsible conduct of research. Applications without plans for instruction in the responsible conduct of research will be considered incomplete and will be returned to the applicant without review.

MINORITY RECRUITMENT AND RETENTION PLAN: The NIH remains committed to increasing the participation of individuals from underrepresented minority groups in biomedical and behavioral research. All competing applications for this Program must include a specific plan to recruit and retain underrepresented minorities in the Career Development Program. In addition, all competing continuation applications must include a report on the recruitment and retention of underrepresented minorities during the previous award period. If an application is received without a plan or without a
report on the previous award period, the application will be considered incomplete and will be returned to the applicant without review.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: February 23, 2004
Application Receipt Date: March 23, 2004
Peer Review Date: June/July 2004
Council Review Date: September 2004
Earliest Anticipated Start Date: September 30, 2004

AWARD CRITERIA

Award decisions will be based upon:

o Scientific merit (as determined by peer review)
o Availability of funds
o Programmatic priorities

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

DATA AND SAFETY MONITORING PLAN: Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness and comparative trials (phase III). The establishment of data and safety monitoring boards (DSMBs) is required for

multi-site clinical trials involving interventions that entail potential risk to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html.)

SHARING RESEARCH DATA: Starting with the October 1, 2003, receipt date, investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing). Investigators should seek guidance from their institutions on issues related to institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan, but will not factor the plan into the determination of the scientific merit or the priority score.

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide, in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: The Department of Health and Human Services (DHHS) issued final modification to the “Standards for Privacy of Individually Identifiable Health Information,” the “Privacy Rule,” on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is

administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.healthypeople.gov/.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Return to Volume Index

Return to NIH Guide Main Index

Department of Health
and Human Services

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892